

MAY 17 2007

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**SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT BY  
APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2 Attorney Docket No. 7541-6

**Complete If Known**

Application Number	10/551,840
Filing Date	January 20, 2006
First Named Inventor	SAMARITANI, Fabrizio et al.
Art Unit	1654
Examiner Name	Khanna, Hemant

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (If known)			
/H.K./		US 4,496,537	01-29-1985	Kwan, Henry K.	
		US 4,589,402	05-20-1986	Hodgen, et al.	
		US 4,659,696	04-21-1987	Hirai, et al.	
		US 4,670,419	06-02-1987	Uda, et al.	
		US 4,746,508	05-24-1998	Carey, et al.	
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		US 4,962,091	10-09-1990	Eppstein, et al.	
		US 5,087,615	02-11-1992	Chappel, et al.	
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		US 5,162,306	11-10-1992	Donaldson	
		US 5,270,057	12-14-1993	de Meere, et al.	
		US 5,356,876	10-18-1994	Espey, Lawrence L	
		US 5,374,620	12-20-1994	Clark, et al.	
		US 5,384,132	01-24-1995	De Meere, et al.	
		US 5,508,261	04-16-1996	Moyle, et al.	
		US 5,580,856	12-03-1996	Prestrelski, et al.	
		US 5,639,640	06-17-1997	Reddy, et al.	
		US 5,650,390	07-22-1997	Samaritani, et al.	
		US 5,661,125	08-26-1997	Strickland, Thomas Wayne	
		US 5,681,822	10-28-1997	Bornstein, et al.	
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		US 5,811,096	09-22-1988	Aleman, et al.	
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		US 6,238,890	05-29-2001	Boime, et al.	
		US 6,267,958	07-31-2004	Andya, et al.	
/H.K./		US 6,440,930	08-27-2002	Rinella, Jr., Vincent Joseph	

Examiner Signature	Date Considered
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/H.K./		US 6,541,606	04-01-2003	Margolin, et al.	
/H.K./		US 6,573,237	06-03-2003	Rinella, Jr., Vincent Joseph	
/H.K./		US 2003/0072803	04-27-2003	Goldenberg, et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
/H.K./		DE 41 17 078 A1	11-25-1882	Lohmann et al.		<input type="checkbox"/>
		EP 0 318 081	05-31-1989	Jansen, et al.		<input type="checkbox"/>
		EP 0 448 146	09-25-1991	De Ruiter, Marinus Arie		<input type="checkbox"/>
		EP 0 603 159	06-22-1994	Pearlman, et al.		<input type="checkbox"/>
		EP 0 652 766	07-29-1993	O'Connor, et al.		<input type="checkbox"/>
		EP 0 668 073	04-14-1999	Igari, et al.		<input type="checkbox"/>
		EP 0 736 303	08-25-1999	Gross, et al.		<input type="checkbox"/>
		EP 0 853 945	07-22-1998	Skrabanja, et al.		<input type="checkbox"/>
		EP 0 891 774	01-20-1999	Takada, et al.		<input type="checkbox"/>
		EP 0 920 873	12-07-1998	Chang, et al.		<input type="checkbox"/>
		EP 0 974 359	01-26-2000	Hoffmann, et al.		<input type="checkbox"/>
		EP 1 191 099	06-30-1999	Itoh, et al.		<input type="checkbox"/>
		CA 1,340,132	11-17-1998	Donaldson, Lloyd E.		<input type="checkbox"/>
		FR 2782455	02-25-2000	Aleman, et al.		<input type="checkbox"/>
		GB 1065127	04-12-1967	Serono 1 <sup>st</sup> Farm		<input type="checkbox"/>
		GB 839,300	08-25-1958	Organon Laboratories Limited		<input type="checkbox"/>
		WO 92/21332	12-10-1992	Lohmann, et al.		<input type="checkbox"/>
		WO 92/22568	12-23-1992	Moyle, et al.		<input type="checkbox"/>
		WO 93/11788	06-24-1993	Samaritani, et al.		<input type="checkbox"/>
		WO 94/03198	02-17-1994	O'Connor, et al.		<input type="checkbox"/>
		WO 97/04801	02-13-1997	Andya, et al.		<input type="checkbox"/>
		WO 97/17087	05-15-1997	De Young, et al.		<input type="checkbox"/>
		WO 98/30592	07-16-1998	Hein, et al.		<input type="checkbox"/>
/H.K./		WO 99/21534	05-06-1999	Tallavajhala, et al.		<input type="checkbox"/>

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Sheet

1

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7

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Examiner Name	Khanna, Hemant

Attorney Docket No. 7541-6

## NON PATENT LITERATURE DOCUMENTS

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/H.K./		AKERS Michael J., "Considerations in selecting antimicrobial preservative agents for parenteral product development", Pharmaceutical Technology, May 1984, pp. 36-46.	<input type="checkbox"/>
		AKERS, Michael J., "Excipient – Drug Interactions in Parenteral Formulations", Journal of Pharmaceutical Sciences, November 2002, Vol. 91, No. 11, pp. 2283-2300	<input type="checkbox"/>
		AMIR, Syed M. et al., "Phenol, A Potent Stimulator of Adenylate Cyclase in Human Thyroid Membranes", Endocrine Research Communications, 8(2):83-95, 1981.	<input type="checkbox"/>
		A.P.L.® Injection 5 000 IU and Injection 10 000 IU, <a href="http://home.intekom.com/pharm/akromed/api-inj.html">http://home.intekom.com/pharm/akromed/api-inj.html</a> , December 12, 2002, pp. 1-2.	<input type="checkbox"/>
		A.P.L.® (chorionic gonadotropin for injection, USP), For Intramuscular Injection Only, Physicians' Desk Reference, 51 <sup>st</sup> Edition, p. 2805.	<input type="checkbox"/>
		A.P.L.®, Physicians' Desk Reference, 12 <sup>th</sup> Edition, page 625.	<input type="checkbox"/>
		A.P.L.®, Physicians' Desk Reference, 19 <sup>th</sup> Edition, page 537.	<input type="checkbox"/>
		A.P.L.®, Physicians' Desk Reference, 34 <sup>th</sup> Edition, page 592.	<input type="checkbox"/>
		ARZNEIFORMENLEHRE, Paul Heinz List, Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart, 4th Edition, 1985, pp. 402-407.	<input type="checkbox"/>
		Asellacrin®, Physicians' Desk Reference, 34 <sup>th</sup> Edition, pp. 1605-1606.	<input type="checkbox"/>
		Asellacrin®, Physicians' Desk Reference, 39 <sup>th</sup> Edition, pp. 1940-1941.	<input type="checkbox"/>
		BOIME, Irving et al., "Glycoprotein Hormone Structure-Function and Analog Design", Recent Progress in Hormone Research, Vol. 54, 1999, The Endocrine Society, pp. 271-289.	<input type="checkbox"/>
		BONTEMPO, John A., "Chapter 5: Formulation Development", Development of Biopharmaceutical Parenteral Dosage Forms, pp. 109-142, published by Marcel Dekker, Inc.	<input type="checkbox"/>
		COMBARNOUS, Yves, "Molecular Basis of the Specificity of Binding of Glycoprotein Hormones to Their Receptors", Endocrine Reviews, 1992, Vol. 13, No. 4, pp. 670-691.	<input type="checkbox"/>
		CPMP Guidelines antimicrobial preservative inclusion, CPMP/CVMP/OWP/115/95, July 8, 1997, pp. 1-6.	<input type="checkbox"/>
↓		de MEDEIROS, S.F. et al., "Stability of Immunoreactive $\beta$ -Core Fragment of hCG", Obstetrics & Gynecology, Vol. 77, No. 1, January 1991, pp. 53-59.	<input type="checkbox"/>
/H.K./		Epogen®, Physicians' Desk Reference, 51 <sup>st</sup> Edition, pp. 489-494.	<input type="checkbox"/>

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<sup>2</sup>Applicant is to place a check mark here if English language Translation is attached#449528



#449528WEMMH PTO/SB/08b (09-06)

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Sheet	2	of	7	Attorney Docket No.	7541-6
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### NON PATENT LITERATURE DOCUMENTS

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/H.K.		Fertinex™ (urofollitropin for injection, purified) for subcutaneous injection, Physicians' Desk Reference, 53 <sup>rd</sup> Edition, pp. 2988-2989, published by Medical Economics Company, Inc.	<input type="checkbox"/>
		Fertinex®, Physicians' Desk Reference, 55 <sup>th</sup> Edition, pp. 3020-3022.	<input type="checkbox"/>
		Follistim™ (follitropin beta for injection), Physicians' Desk Reference, 53 <sup>rd</sup> Edition, pp. 2128-2132, published by Medical Economics Company, Inc.	<input type="checkbox"/>
		Follistim®, Physicians' Desk Reference, 54 <sup>th</sup> Edition, pp. 2092-2095.	<input type="checkbox"/>
		Follutein®, Physicians' Desk Reference, 24 <sup>th</sup> Edition, pp. 1249-1250.	<input type="checkbox"/>
		FRANSSON, Jonas et al., "Solvent Effects on the Solubility and Physical Stability of Human Insulin-Like Growth Factor 1", Pharmaceutical Research 14(5):606-12, 1997.	<input type="checkbox"/>
		FRENKEN, L.A.M. et al., "Analysis of the Efficacy of Measures to Reduce Pain After Subcutaneous Administration of Epoetin Alfa", Nephrology Dialysis Transplantation 9:1295-98, 1994.	<input type="checkbox"/>
		FURUHASHI, M. et al. "Fusing the Carboxy-Terminal Peptide of the Chorionic Gonadotropin (CG) beta Subunit to the Common alpha-Subunit: Retention of O-linked Glycosylation and Enhanced in Vivo Bioactivity of Chimeric Human CG", Molecular Endocrinology, 1995, Vol. 9, No. 1, pages 54-63.	<input type="checkbox"/>
		GARCIA-CAMPAYO, Vincenta et al., "Design of Stable Biologically Active Recombinant Lutropin Analogs", Nature Biotechnology 15:663-67, 1997.	<input type="checkbox"/>
		GENNARO et al., "Parenteral Preparations", Chapter 84, Remington's Pharmaceutical Sciences (18th Edition, Mack Publishing Co., 1990, see part 8 "Pharmaceutical Preparations and their Manufacture," pp. 1545-1569.	<input type="checkbox"/>
		Glucagon, Physicians' Desk Reference, 19 <sup>th</sup> Edition, pp. 703-704.	<input type="checkbox"/>
		Glukor®, Physicians' Desk Reference, 19 <sup>th</sup> Edition, page 844.	<input type="checkbox"/>
		Gonal-F®, (follitropin alfa for injection), for subcutaneous injection, Physicians' Desk Reference, 53 <sup>rd</sup> Edition, pp. 2991-2995, published by Medical Economics Company, Inc.	<input type="checkbox"/>
		Gonal-F® (follitropin alfa for injection) For subcutaneous injection: Package Insert Code N1900101B, manufactured by Serono Laboratories, Inc., Randolph, MA, USA, published September, 1997.	<input type="checkbox"/>
✓		Gonal-F®, Physicians' Desk Reference, 54 <sup>th</sup> Edition, pp. 2942-2946.	<input type="checkbox"/>
/H.K./		HANSON, Musetta A. et al., "Introduction to Formulation of Protein Pharmaceuticals", Chapter. 7, pp. 209 – 233.	<input type="checkbox"/>

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<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Application Number	10/551,840
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Sheet	3	of	7	Attorney Docket No. 7541-6	

#### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T <sup>2</sup>
/H.K./		HARVEY, Stewart C., "Antiseptics and Disinfectants; Fungicides; Ectoparasiticides", The Pharmacological Basis of Therapeutics, 6 <sup>th</sup> Edition, Chapter 41, 964-987, 1980.	<input type="checkbox"/>
		HEIKOOP, Judith C. et al., "Structure-based design and protein engineering of intersubunit disulfide bonds in gonadotropins" Nature Biotechnology, July 1997, Volume 15, pp. 658-62.	<input type="checkbox"/>
		Package insert HRF, "HRF* Injection 0,1 mg and HRF* Injection 0,5 mg", Malahyde Information Systems, 2003, pp.1-4.	<input type="checkbox"/>
		Humatrop <sup>®</sup> , Physicians' Desk Reference, 44 <sup>th</sup> Edition, pp. 1216-1217.	<input type="checkbox"/>
		Humegon <sup>®</sup> , Physicians' Desk Reference, 54 <sup>th</sup> Edition, pp. 2095-2097.	<input type="checkbox"/>
		JORGENSON, Jan Trost, "Improvement of Patient Convenience in Treatment with Growth Hormone", Journal of Pediatric Endocrinology, 1994, 7(2):175-180.	<input type="checkbox"/>
		KEENE et al., Expression of Biologically Active Human Follitropin in Chinese Hamster Ovary Cells. The Journal of Biological Chemistry Vol. 264/9: 4769-4775.	<input type="checkbox"/>
		KESNER, J.S. et al., "Stability of Urinary Female Reproductive Hormones Stored Under Various Conditions", Reproductive Toxicology, Vol. 9, No. 3, pp. 239-244, 1995.	<input type="checkbox"/>
		LAM, Xanthe M. et al., "The Effect of Benzyl Alcohol on Recombinant Human Interferon- $\gamma$ " Pharmaceutical Research, 1997, Vol. 14, No. 6, 725-729.	<input type="checkbox"/>
		LEUKINE Package Insert/Approved Text, Rev. 0230-02, Issued February, 1998, pp 1-30.	<input type="checkbox"/>
		LIVESEY J. H. et al., "Glycerol prevents loss of immunoreactive follicle-stimulating hormone and luteinizing hormone from frozen urine", Journal of Endocrinology, Vol. 98, pp. 381-384, 1983.	<input type="checkbox"/>
		LIVESEY, J. H. et al., "Effect of Time, Temperature and Freezing on the Stability of Immunoreactive LH, FSH, TSH, Growth Hormone, Prolactin and Insulin in Plasma", The Medical Unit, Princess Margaret Hospital, Christchurch 2, New Zealand, June 25, 1980, Biochem 13 (4), 1980, pp. 151-155.	<input type="checkbox"/>
		MAA, Yuh-Fun, et al., "Aggregation of recombinant human growth hormone induced by phenolic compounds", International Journal of Pharmaceutics, 1996, Vol. 140, pp. 155 – 168.	<input type="checkbox"/>
▼		Metrodin <sup>®</sup> , Physicians' Desk Reference, 51 <sup>st</sup> Edition, pp. 2616-2618.	<input type="checkbox"/>
/H.K./		Pergonal <sup>®</sup> , Physician's Desk Reference, 29 <sup>th</sup> Edition, pp. 1366-1367.	<input type="checkbox"/>

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/H.K.		Pergonal®, Physician's Desk Reference, 49 <sup>th</sup> Edition, pp. 2335-2337.	<input type="checkbox"/>
		Pergonal®, Physician's Desk Reference, 51 <sup>st</sup> Edition, pp. 2618-2620.	<input type="checkbox"/>
		Pergonal®, Physician's Desk Reference, 54 <sup>th</sup> Edition, pp. 2946-2947.	<input type="checkbox"/>
		PIMPALKHUTE, M. et al., "Radioimmunoassay of Human Follicle Stimulating Hormone/HFSH", J. Radioanal. Nucl. Chem. Letters, 1986, 103, No. 2, pp. 105-116.	<input type="checkbox"/>
		Pregnyl®, Physicians' Desk Reference, 39 <sup>th</sup> Edition, page 1450.	<input type="checkbox"/>
		Pregnyl® (chorionic gonadotropin for injection, USP), Physicians' Desk Reference, 51 <sup>st</sup> Edition, p. 1878.	<input type="checkbox"/>
		Pregnyl Prescribing Information, "Pregnyl (chorionic gonadotropin for injection, USP), Organon Inc., August 1998, pp. 1-4.	<input type="checkbox"/>
		Procrit®, Physicians' Desk Reference, 51 <sup>st</sup> Edition, page 1896.	<input type="checkbox"/>
		Profasi® (chorionic gonadotropin for injection, USP) for Intramuscular Injection, Physicians' Desk Reference, 51 <sup>st</sup> Edition, pp. 2620-21.	<input type="checkbox"/>
		Profasi (chorionic gonadotropin for injection, USP) for intramuscular injection, Serono Laboratories, Inc. (revised June 1993).	<input type="checkbox"/>
		Progon®, Physicians' Desk Reference, 19 <sup>th</sup> Edition, page 646.	<input type="checkbox"/>
		Protropin®, Physicians' Desk Reference, 44 <sup>th</sup> Edition, pp. 1002-1003.	<input type="checkbox"/>
		RAFFERTY, M.J. et al., "Safety and Tolerability of a Multidose Formulation of Epoetin Beta in Dialysis Patients", Clinical Nephrology, 54(3):240-45, 2000.	<input type="checkbox"/>
		Regular Iletin®, Physicians' Desk Reference 19 <sup>th</sup> Edition, page 705.	<input type="checkbox"/>
▼		REMMELE Jr., Richard L. et al., "Interleukin-1 Receptor (IL-1R) Liquid Formulation Development Using Differential Scanning Calorimetry", Pharmaceutical Research, 1998, Vol. 15, No. 2 pp. 200-208.	<input type="checkbox"/>
/H.K.		ROSE, M.P. et al, "Characterisation, calibration and comparison by international collaborative study of international standards for the calibration of therapeutic preparations of FSH", Journal of Endocrinology, Vol. 158, pp. 97-114, 1998.	<input type="checkbox"/>

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Attorney Docket No. 7541-6

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T <sup>2</sup>
/H.K./		RYAN, Robert J. et al., "Some physical and Hydrodynamic Properties of Human FSH and LH", Mayo Clinic and Mayo Foundation: Section of Endocrine Research, Rochester, Minnesota; and Department of Biochemistry, University of Illinois, Chicago, Illinois, pp. 105-137.	<input type="checkbox"/>
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		SAKETOS, Maria et al., "Time-Resolved Immunofluorometric Assay and Specimen Storage Conditions for Measuring Urinary Gonadotropins", Clinical Chemistry, Vol. 40, No. 5, 1974, pp. 749-753.	<input type="checkbox"/>
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Examiner Signature	Date Considered
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Substitute for form 1449A/PTO				Complete if Known	
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Application Number	10/551,840
				Filing Date	January 20, 2006
				First Named Inventor	SAMARITANI, Fabrizio et al.
				Art Unit	1654
				Examiner Name	Khanna, Hemant
Sheet	6	of	7	Attorney Docket No.	7541-6

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		BAM, Narendra B. et al. "Stability of Protein Formulations: Investigation of Surfactant Effects by a Novel EPR Spectroscopic Technique", Research Article, Pharmaceutical Research, Vol. 12, No. 1, 1995, pp. 2-11.	<input type="checkbox"/>
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		BOULET, Louis-Philippe et al., "Inhibitory Effects of an Anti-IgE Antibody E25 on Allergen-induced Early Asthmatic Response", Am J Respir Crit Care Med., Vol. 155, 1997, pp. 1835-1840.	<input type="checkbox"/>
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		JENTOFT, Neil, "Why are proteins O-glycosylated?", TIBS 15, August 1990, Elsevier Sciences Publishers Ltd. (UK), pp. 291-294.	<input type="checkbox"/>
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		KIBBE, Arthur H. (Editor), "Benzyl Alcohol", Handbook of Pharmaceutical Excipients, Third Edition, American Pharmaceutical Association, 2000, pp.41-43.	<input type="checkbox"/>
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7

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/H.K./		PIKAL, Michael J. et al., "The Effects of Formulation Variables on the Stability of Freeze-Dried Human Growth Hormone", Pharmaceutical Research, Vol. 8, No. 4, 1991, pp. 427-436.	<input type="checkbox"/>
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		STANKOV, B. M. et al., "The Effect of the Purity of the Iodinated Tracer on the Specificity of a Homologous Assay of Ovine Follicle Stimulating Hormone", Biochemistry International, Vol. 12, No. 1, January 1986, pp.11-19.	<input type="checkbox"/>
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/H.K./		XING, Yongna et al., "Threading of a glycosylated protein loop through a protein hole: Implications for combination of human chorionic gonadotropin subunits", Protein Science, Vol. 10, 2001, pp. 226-235.	<input type="checkbox"/>

Examiner Signature	/Hemant Khanna/	Date Considered	07/14/2007
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